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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2005D–0310]

Draft Guidance for Industry on Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events," dated August 2005. The draft guidance provides sponsors of gene therapy studies with recommendations regarding collection of data on delayed adverse events in participants who have been exposed to gene therapy products. When finalized, this guidance will supplement the recommendations in the "Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors" (Retroviral Vector guidance), dated October 2000, for study participant long-term followup. However, the recommendations in the Retroviral Vector guidance regarding the length of followup will be superseded by this Gene Therapy Clinical Trials guidance.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**] to ensure their

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adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events" dated August 2005. This draft guidance provides to sponsors of gene therapy studies recommendations on: (1) Methods to assess the risk of gene-therapy-related delayed adverse events following exposure to gene therapy products, (2) guidance for determining the likelihood that long-term followup observations on study participants will provide scientifically

meaningful information, and (3) specific advice regarding the duration and design of long-term followup observations.

This draft guidance, when finalized, will supplement the recommendations in the "Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors" (Retroviral Vector guidance), dated October 2000, for study participant long-term followup. However, the recommendations in the Retroviral Vector guidance regarding the length of followup will be superseded by this Gene Therapy Clinical Trials guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection provisions in this guidance for the investigational new drug application (IND) regulations (21 CFR part 312) have been approved under OMB control number 0910–0014; and the good laboratory practice (GLP) regulations (21 CFR part 58) have been approved under OMB control number 0910–0119.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit

to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: 8/12/05

August 12, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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